DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-747/S-002

Aventis Pharmaceuticals Products Inc.
Attention: Kimberly A. Davis
Senior Regulatory Affairs Analyst
Mail Drop: SCC3-735A
Somerset Corporate Center
300 Somerset Corporate Boulevard
Bridgewater, NJ 08807-2854

Dear Ms. Davis:

Please refer to your supplemental new drug application dated February 14, 2000, received February 16, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Synercid® I.V. (quinupristin and dalfopristin for injection). We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated April 6, 2000, and May 7, 2001.

This supplemental new drug application provides for the following revisions to the **Microbiology** subsection of the **CLINICAL PHARMACOLOGY** section of the labeling:

1. Changes the quality control range for *Staphylococcus aureus*, ATCC 25923, from 23-29mm to 21-28 mm.

2. Deletes the redundant sentence in the **SUSCEPTIBILITY TESTING** section, **Diffusion Techniques** subsection, regarding Mueller Hinton agar.

3. Minor editorial changes as requested by the FDA in the Memorandum dated November 9, 1999 and those identified by Aventis.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

Additionally, we have completed our review of the final printed labeling (FPL) submitted May 7, 2001 (#50059555/595385 Rev. 12/00) and find it acceptable. However, it is requested that at the next printing of the labeling the following editorial revision be made:

In the **PRECAUTIONS** section, **Hyperbilirubinemia** subsection, revise "…non-comparative studies (see **CLINICAL STUDIES: Non-Comparative Trials**)." To read "…non-comparative studies. (See **CLINICAL STUDIES: Non-Comparative Trials**.)"

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Maureen Dillon-Parker, Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Janice Soreth

3/13/02 11:57:16 AM